REMARKS

Any fees that may be due in connection with the filing of this paper or with this application should be charged to Deposit Account No. 02-1818. If a Petition for extension of time is needed, this paper is to be considered such Petition.

Claims 1-11, 37-40 and 42-53 are pending. Claim 41 is cancelled without prejudice or disclaimer. Claims 42-53 are added herein. Basis for claims 42 and 43 is found, *e.g.*, at page 10, lines 16-19. Basis for claims 44-46 is found, *e.g.*, at page 9, lines 4-8; page 13, lines 19-24; and at page 14, lines 24-27. Basis for claim 47 is found, *e.g.*, at page 10, lines 27-29. Basis for claims 48, 49, 52 and 53 is found, *e.g.*, at page 9, lines 4-8 and page 14, lines 24-27. Basis for claims 50 and 51 is found, *e.g.*, at page 8, lines 16-29 and original claims 3-5.

No new matter has been added.

REJECTION OF CLAIMS UNDER 35 U.S.C. 103(a)

In the previous Office Action, pending claims 1-11 and 37-39 were rejected under 35 U.S.C. 103 (a) as unpatentable over Kawakami (JP 05306221) in view of Colliopoulos (US 5,232,699) in view of Cockerill (US 4,452,779) because Kawakami allegedly teaches every element of the claims except xylose as a minimally degradable sugar, magnesium sulfate as a water-soluble magnesium salt and a hypertonic aqueous solution, but Colliopoulos and Cockerill allegedly teach the elements missing from Kawakami. The Examiner alleges that it would have been obvious to one of ordinary skill in the art to have combined the teachings of Kawakami, Colliopoulos and Cockerill and to have added xylose as a minimally degradable sugar in the composition of Kawakami and to use magnesium sulfate as a water-soluble magnesium salt in a hypertonic solution (claim 8). The Examiner contends that the selection of the weight ratios is merely a matter of judicious selection and routine optimization.

Applicant respectfully submits that the combination of the teachings of Kawakami and Colliopoulos and Cockerill does not result in the claimed compositions and methods of claims 42-53.

ANALYSIS

The combination of the teachings of Kawakami and Colliopoulos and Cockerill does not result in the claimed compositions and methods

The arguments set forth in the Response, filed March 15, 2010, are incorporated by reference herein. Added claims 42-47 are composition claims that ultimately depend from claim 1 and incorporate every limitation thereof. Added claims 48-53 are method claims that

include as an element administration of a compound of claim 1 or claim 8. Thus, for the same reasons of record that the combination of the teachings of Kawakami and Colliopoulos and Cockerill does not teach or suggest every element of the compositions of claims 1-11 and 37-41, the combination of Kawakami and Colliopoulos and Cockerill also fails to teach or suggest every element of the compositions of claims 42-47 and the methods of claims 48-53.

In addition, as demonstrated in the Declaration of Dr. Borody provided with the Response, filed March 15, 2010, purgatives that are within the scope of claim 1 and its dependent claims exhibit properties not taught or suggested in the cited art. The tested purgative compositions within the scope of claim 1 were determined to be effective at cleaning the bowel and, as judged by Dr. Borody, superior in cleansing ability, and shown to be faster at initiating bowel evacuation and to cause fewer adverse side effects, such as nausea, vomiting and headaches, when compared to purgative compositions similar to the composition described in Kawakami. The compositions of claims 42-47 and the compositions administered in the methods of claims 48-53 are compositions within the scope of claim 1.

None of Kawakami or Colliopoulos or Cockerill, singly or in any combination, nor any art of record, teaches or suggests any combination of water soluble sodium, potassium and magnesium salts and minimally degradable sugar(s) in the recited weight ratios or that such a combination would result in a composition that exhibits a significant improvement in bowel cleansing, a faster time to initiation of bowel cleansing, and fewer adverse side effects than is achieved using the PicoPrep™ composition, which is comparable to the composition described in Kawakami when administered with a degradable sugar. Therefore, compositions of claims 42-47 and the compositions administered in the methods of claims 48-53, which are compositions within the scope of claim 1, cannot be obvious in view of the cited references.

In addition, as discussed below, claims 42-53 also are patentable for other reasons.

Claims 42 and 43

Claims 42 and 43 recite compositions that include, in addition to the combination of water soluble sodium, potassium and magnesium salts and minimally degradable sugar(s), sodium picosulfate as an additional ingredient. Sodium picosulfate is a laxative that stimulates bowel movement, generally making bowel movements looser and more frequent. Kawakami does not teach or suggest, among other elements, a purgative composition that contains sodium

picosulfate. There is no mention of sodium picosulfate in Kawakami. Neither of the secondary references teaches or suggests the elements missing from Kawakami.

Colliopoulos teaches baked wafer laxative compositions containing psyllium and senna or sennosides. The compositions of Colliopoulos do not include sodium picosulfate. There is no teaching or suggestion in Colliopoulos to add sodium picosulfate to a purgative composition of Kawakami. Thus, combining the teachings of Kawakami and Colliopoulos does not result in the compositions of claims 42 and 43.

Cockerill does not cure the deficiencies in the combination of the teachings of Kawakami and Colliopoulos. The compositions of Cockerill do not include sodium picosulfate. Cockerill does not teach or suggest including sodium picosulfate in any formula. Neither Colliopoulos nor Cockerill teaches or suggests anything regarding sodium picosulfate. Neither Colliopoulos nor Cockerill, alone or in combination, teaches or suggests a composition that contains, or would lead one of ordinary skill in the art to modify the composition of Kawakami so that it contains, sodium picosulfate. Therefore, for at least these reasons, the combination of the teachings of Kawakami and Colliopoulos and Cockerill does not teach or suggest every element of the compositions of claims 42 and 43.

Further, as demonstrated in the Declaration of Dr. Borody provided with the Response, filed March 15, 2010, purgatives that are within the scope of claim 1 that include sodium picosulfate exhibit properties not taught or suggested in the cited art. Tested compositions within the scope of instant claim 1 that included sodium picosulfate exhibited a significant improvement in bowel cleansing, a faster time to initiation of bowel cleansing, and fewer adverse side effects than is achieved using the PicoPrep™ composition, which includes sodium picosulfate and is comparable to the composition described in Kawakami when administered with a degradable sugar. Thus, compositions that are comparable to the compositions of Kawakami that also include sodium picosulfate did not exhibit any improvement in bowel cleansing, any decrease in time to initiation of bowel cleansing, or any reduction in adverse side effects. None of Kawakami or Colliopoulos or Cockerill, singly or in any combination, teaches or suggests that purgative compositions that include sodium picosulfate and the instantly claimed range and ratio of water soluble sodium, potassium and magnesium salts and minimally degradable sugar(s) produce such results. Therefore, claims 42 and 43 cannot be obvious in view of the cited references.

Claims 44-46

Claims 44-46 recite compositions that include, in addition to the combination of water soluble sodium, potassium and magnesium salts and minimally degradable sugar(s), bisacodyl as an additional ingredient. Bisacodyl is a laxative that stimulates bowel movement by altering intestinal fluid and electrolyte absorption and can cause abdominal pain, cramps, nausea or vomiting (Accarino, "Motility Drug Uses: Bisacodyl," European Digestive Motility Centre: Research & Investigation (2005), a copy of which is attached). Kawakami teaches that fluctuation of the electrolyte balance in the body causes side effects and that its compositions avoid fluctuations in electrolyte balance. The composition taught by Kawakami does not teach or suggest, among other elements, a purgative composition that contains bisacodyl. Neither of the secondary references teaches or suggests the elements missing from Kawakami.

Colliopoulos teaches baked wafer laxative compositions containing psyllium and senna or sennosides. The compositions of Colliopoulos do not include bisacodyl. There is no teaching or suggestion in Colliopoulos to add bisacodyl to a purgative composition of Kawakami. Thus, combining the teachings of Kawakami and Colliopoulos does not result in the compositions of claims 44-46.

Cockerill does not cure the deficiencies in the combination of the teachings of Kawakami and Colliopoulos. The compositions of Cockerill do not include bisacodyl. Cockerill does not teach or suggest including bisacodyl in any formula. Neither Colliopoulos nor Cockerill teaches or suggests anything regarding bisacodyl. Neither Colliopoulos nor Cockerill, alone or in combination, teaches or suggests a composition that contains, or would lead one of ordinary skill in the art to modify the composition of Kawakami so that it contains, bisacodyl. Therefore, for at least these reasons, the combination of the teachings of Kawakami and Colliopoulos and Cockerill does not teach or suggest every element of the compositions of claims 44-46.

In addition, in light of the teachings of Kawakami, which states that fluctuation in electrolyte balance in the body causes adverse side effects and that its formulations are formulated to avoid fluctuation in electrolyte balance, any modification of the Kawakami composition to include bisacodyl, which alters intestinal fluid and electrolyte absorption and thus causes fluctuation in electrolyte balance in the body, would render it unsatisfactory, due to the undesirable side effects taught by Kawakami. Thus, there can be no suggestion or motivation to make such a modification (*In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)), since such modification is taught by Kawakami to be undesirable. Therefore, the

teachings of the references cannot render claims 44-46 *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Claim 47

Claim 47 recites a purgative composition of claim 1 in the form of a tablet, where the tablet includes a core containing the sodium, potassium and magnesium salts; and a coating containing the minimally degradable sugar(s); where the coating surrounds the core. Kawakami teaches that its composition is dissolved in 900 mL of water to provide a purgative that is isotonic (paragraphs [0017] and [0018]) or is dried and pulverized into a powder (paragraph [0021]). There is no teaching or suggestion in Kawakami to provide a purgative composition in the form of a tablet as claimed in claim 47, having a core that includes sodium, potassium and magnesium salts in the recited range and ratio, surrounded by a coating containing minimally degradable sugar(s). Neither of the secondary references teaches or suggests the elements missing from Kawakami.

Colliopoulos teaches a laxative composition in the form of a baked wafer. Colliopoulos does not teach or suggest any tablet and certainly does not teach or such modifying an isosmolar solution or powder of Kawakami to make it into a tablet in which sodium, potassium and magnesium salts in the recited range and ratio make up the core, which is surrounded by a coating containing minimally degradable sugar(s). Thus, combining the teachings of Kawakami and Colliopoulos does not result in the composition of claim 47.

Cockerill does not teach or suggest the elements missing from the combination of Kawakami and Colliopoulos. Cockerill teaches dry powdered compositions that are mixed with the feed of a lactating mammal. There is no teaching or suggestion of a purgative in the form of a tablet in Cockerill. Thus, combining the teachings of Kawakami and Colliopoulos and Cockerill, alone or in any combination, does not teach or suggest a purgative in the form of a tablet as recited in claim 47. Therefore, the combination of the teachings of Kawakami and Colliopoulos and Cockerill does not teach or suggest every element of claim 47.

Claims 48, 49, 52 and 53

Claims 48, 49, 52 and 53 recite methods that include administering the composition of claim 1 or claim 8 in combination with sodium picosulfate or bisacodyl. Kawakami teaches administering its isotonic composition to irrigate the intestinal canal. As discussed above, the composition of Kawakami does not include sodium picosulfate or bisacodyl. Kawakami does not teach or suggest administering its purgative in the form of an isotonic composition in

combination with sodium picosulfate or bisacodyl. Neither of the secondary references teaches or suggests the elements missing from Kawakami.

Colliopoulos teaches administering its baked wafer compositions containing psyllium and senna or sennosides to achieve a laxative effect. There is no teaching or suggestion in Colliopoulos to administer sodium picosulfate or bisacodyl in combination with its wafer compositions or with any purgative composition, such as the composition of Kawakami. Thus, combining the teachings of Kawakami and Colliopoulos does not result in the methods of claims 48, 49, 52 and 53.

Cockerill does not cure the deficiencies in the combination of the teachings of Kawakami and Colliopoulos. The methods of treating lactating mammals described in Cockerill do not include administering sodium picosulfate or bisacodyl. Cockerill does not teach or suggest administering sodium picosulfate or bisacodyl in combination with any purgative composition. Neither Colliopoulos nor Cockerill teaches or suggests anything regarding sodium picosulfate or bisacodyl. Neither Colliopoulos nor Cockerill, alone or in combination, teaches or suggests a method that includes as a step, or would lead one of ordinary skill in the art to modify the methods of Kawakami so that it includes as a step, administering sodium picosulfate or bisacodyl in combination with a purgative. Therefore, for at least these reasons, the combination of the teachings of Kawakami and Colliopoulos and Cockerill does not teach or suggest every element of the methods of claims 48, 49, 52 and 53.

Claims 50 and 51

Claims 50 and 51 recite methods of inducing purgation of claim 1 and 8, respectively, where the purgative composition that is administered includes potassium chloride. Kawakami teaches that when potassium chloride is added to a magnesium citrate isotonic solution, an indescribably bad taste is produced (paragraph [0011]). Kawakami teaches administering its compositions as a purgative, and its compositions are magnesium citrate isotonic solutions. Thus, Kawakami specifically teaches not to add potassium chloride to its compositions because such addition results in undesirable side-effects.

Colliopoulos teaches administering its baked wafer compositions containing psyllium and senna or sennosides to achieve a laxative effect. There is no teaching or suggestion in Colliopoulos to include potassium chloride in its wafer compositions or with any magnesium citrate based purgative composition, such as the composition of Kawakami. Thus, combining the teachings of Kawakami and Colliopoulos does not result in the methods of claims 50 and 51.

Cockerill does not cure the deficiencies in the combination of the teachings of Kawakami and Colliopoulos. Cockerill teaches including a non-toxic diuretic salt in an amount effective for drawing excess fluid from mammary tissue of a lactating mammal into the urinary tract of the lactating mammal. Cockerill does not teach or suggest adding potassium chloride to any magnesium citrate-based purgative composition, such as the composition of Kawakami. Neither Colliopoulos nor Cockerill, alone or in combination, teaches or suggests a method that would lead one of ordinary skill in the art to modify the methods of Kawakami to administer a magnesium citrate-based purgative composition that includes potassium chloride.

In light of the teachings of Kawakami, which states that addition of potassium chloride to an isotonic magnesium citrate aqueous solution results in a product having an indescribably bad taste, any modification of the Kawakami composition to include potassium chloride would render it unsatisfactory in methods of inducing purgation, due to the alleged undesirable side effects taught by Kawakami. Thus, there can be no suggestion or motivation to make such a modification (*In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)), since such modification is taught by Kawakami to be undesirable. Therefore, the teachings of the references cannot render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Therefore, for at least these reasons, the combination of the teachings of Kawakami and Colliopoulos and Cockerill does not teach or suggest every element of the methods of claims 50 and 51.

* * *

In view of the remarks herein, entry of this amendment and allowance of the application respectfully are requested.

Respectfully submitted,

Stephanie Seidman
Reg. No. 33,779

Attorney Docket No. 3800027-00002 / 3703US
Address all correspondence to:
77202
Stephanie Seidman
K&L Gates LLP
3580 Carmel Mountain Road, Suite 200
San Diego, California 92130
Telephone: (858) 509-7410
Facsimile: (858) 509-7460
email: stephanie.seidman@klgates.com

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Motility Drug Uses: Bisacodyl

Last update: 09-Mar-2005

Dr Accarino, Ana

07-Jul-2004

Type/family

Bisacodyl is a laxative. Laxatives can be classified according to their mode of action in:

- Stimulant laxatives
- Bulk forming laxatives
- Osmotic laxatives
- Lubricating agents
- Others

Stimulant laxatives include:

- Diphenols (eg bisacodyl)
- Anthracenes (eg senna preparations)
- Fatty Acids (eg Castor oil)

Bisacodyl, a derivative of diphenylmethane, is a stimulant laxative used to treat constipation.

Bisacodyl was approved by the FDA in October 1957. In 1998, the FDA proposed to reclassify bisacodyl from Category I (generally recognized as safe and effective) to Category III (further testing is required), until more data regarding safety and efficacy were available. The final OTC laxative monograph rule, effective November 5, 2002, stated that data were submitted to the FDA regarding bisacodyl's safety and efficacy as an OTC laxative, and that future publications would address the drug's role as an acceptable OTC laxative. In 1999, bisacodyl tannex formulations were withdrawn from the US market.

Main Indications in motility disorders

- Functional or idiopathic constipation
- Facilitating bowel movements in patients with slow transit constipation, tumours, spinal cord injury, haemorrhoids and other medical conditions with an effect on gastrointestinal motility. This includes drug induced constipation, for example by opioid therapy for pain of both cancer and non-cancer origin or by antidepressants.
- On a laxative ladder, stimulant laxatives such as bisacodyl should be reserved for patients with severe constipation who do not have a response to fibre or osmotic laxatives.
- Bisacodyl laxatives and lavage solutions are also used for colon preparation and evacuation of the bowels after toxic ingestions.

Action on the gastrointestinal tract

Stimulant laxatives are believed to produce laxation by directly stimulating peristaltic movement of the intestine via local mucosal irritation, thus increasing motility. Recent studies suggest that bisacodyl promotes evacuation of the colon by altering intestinal fluid and electrolyte absorption. This causes a net intestinal fluid accumulation and produces laxation.

Standard dosages

Oral dosage:

- Adults and children >= 12 years: 5-15 mg PO given in the evening or before breakfast. Up to 30 mg may be used for more thorough fecal evacuation prior to bowel procedures or surgery.
- Children 3-11 years: 5-10 mg PO or 0.3 mg/kg PO once daily. Oral dosage for children is limited by ability to swallow tablets whole.
- Children < 3 years: Do not use oral route.

Rectal dosage:

- Adults and children >= 12 years: 1 suppository (10 mg) PR, as needed, or 10 mg as a retention enema.
- Children 3-11 years: ½-1 suppository (5-10 mg) PR. Use of retention enema is not recommended.
- Children < 3 years: ½ a suppository (5 mg) PR. Do not use retention enema.

Pharmacokinetics
Absorption & Distribution

Bisacodyl is administered either orally or rectally. Bisacodyl is minimally absorbed (15%), and the onset of action of the drug begins 5-10 hours after an oral dose (depending on stomach content) and 15—60 minutes after rectal administration. Bisacodyl distributes locally, and the circulating drug undergoes hepatic metabolism and is then excreted in the urine.

Contraindications
Warnings/Precautions

Bisacodyl is contraindicated for use in patients with known or suspected GI obstruction or ileus; GI perforation; toxic colitis or toxic megacolon. Patients with symptoms suggestive of bowel obstruction (e.g., acute abdomen or symptoms of appendicitis, abdominal pain, distension, nausea, or vomiting) should be evaluated prior to initiating laxative therapy.

Use bisacodyl with caution in the presence of severe ulcerative colitis or other conditions where there may be compromised integrity of the bowel wall (e.g., diverticulitis, rectal fissures). Stimulant laxatives may aggravate these conditions, and may (rarely) result in bowel perforation in such patients. In a patient with fecal impaction, the administration of a stimulant laxative is not likely to produce disimpaction, and other known effective methods should be employed.

Main side effects (adverse reactions)

Short-term usage of bisacodyl (at normal dosages) typically results in abdominal pain or cramps, faintness, nausea/vomiting, or mild abdominal discomfort. Rectal suppositories of bisacodyl may cause rectal burning and mild proctitis.

Stimulant laxatives like bisacodyl can cause GI irritation, fluid and electrolyte loss (e.g., hypokalemia) and diarrhea, particularly with prolonged use. There is no evidence to support the theory that prolonged use of stimulant laxatives can result in physiological dependence on the laxative ('cathartic colon'), leading to constipation when use is interrupted. Prolonged use of stimulant laxatives containing anthraquinones may lead to melanosis coli – a brown-black pigmentation of the colonic mucosa. This condition is benign and does not lead to colon cancer or other colon abnormalities.

Main drug interactions

The concomitant use of bisacodyl oral tablets with certain food products (e.g., milk and milk products) or with certain drugs that raise gastric pH (e.g., antacids, proton pump inhibitors (PPIs), or H2-blockers) can cause the enteric coating of the bisacodyl tablets to dissolve prematurely, leading to possible gastric irritation or dyspepsia. When taking bisacodyl tablets, it is advisable to avoid ingesting milk products or the above drugs within 1 hour before or after the bisacodyl dosage.

Tachyphylaxis

There is no evidence of tachyphylaxis although one recent review of IBS suggested that stimulant cathartics such as bisacodyl and senna are more likely than other laxative agents to cause cramping and are associated with both tachyphylaxis and dependency (1).

Alternative drugs/therapies

Stimulant laxatives

There are a large number of stimulant laxatives on the market. Their dosing is different for different products and mode of administration (oral, suppository, enema).

- **Senna**
  - Type: anthracenes
  - Dosage: 187 mg daily
- **Cascara sagrada**
  - Type: anthracenes
  - Dosage: 3-6 ml/125 mg day
- **Casanthranol**
  - Type: anthracenes
  - Dosage: 30-60 mg
- **Castor oil**
  - Type: Lubricant/fatty acid
  - Dosage: 15-30 ml per day
- **Mineral oil**
  - Type: Lubricant/fatty acid
  - Dosage: 5-15 ml PO every night

- **Sodium picosulfate**
  - Type: Diphenols
  - Dosage: 5-15 mg every night

- **Docusate sodium**
  - Type: Stool softener
  - Dosage: 100 mg twice per day

Effects on pregnancy

The safety of using bisacodyl during pregnancy has not been determined. Occasional use at recommended doses during pregnancy is not expected to produce teratogenic effects. The safest first-line treatments to use during pregnancy are those that are not absorbed systemically (e.g., fibre, bulk-forming laxatives) in order to minimize drug exposure to the fetus. The indiscriminate use of some stimulant laxatives during pregnancy may induce pre-term labour secondary to the stimulant action on the colon.

It is not known if bisacodyl distributes to the breast milk. The American Academy of Paediatrics has not determined if bisacodyl use is compatible with breast-feeding. Caution is advised when using bisacodyl during lactation; safer laxatives during lactation are those that are not absorbed and those should be considered as first-line therapy for constipation.

Cost/cost effectiveness

No data on specific cost effectiveness of bisacodyl are available – It is an old drug, first approved by the FDA in 1957. The economic impact of constipation is large. In the USA, the condition prompts an estimated 2.5 million physician visits per year, with 100,000 referrals to gastroenterologists. Almost all (85%) of these physician visits result in a prescription for a laxative. Each year, Americans spend almost $1 billion on laxatives.

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Last update: 09-Mar-2005. No follow-up available on this drug.

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